DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

San Francisco District
1431 Harbor Bay Parkway
Alameda, California 94502-7070
Telephone: 510-337-6700

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Our Reference: 2939220

September 19, 1997

Test Ref: GI60709

Arthur Nishimura, Service Manager
Hawaii Pacific X-ray Corporation
815 Waimanu Street #329
Honolulu, Hawaii 96813

WARNING LETTER

Dear Mr. Nishimura:

On June 25, 1997, a Food and Drug Administration (FDA) field test was performed of certified diagnostic x-ray equipment which your firm assembled on January 10, 1997, and reported on Report of Assembly of a Diagnostic X-ray System (Form FDA 2579), [redacted]. The State of Hawaii tested this equipment to determine its compliance with portions of the Federal Performance Standard for Diagnostic X-Ray Equipment (Title 21, Code of Federal Regulations (CFR), sections 1020.30-32). Diagnostic x-ray equipment is a device as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act). The field test, reference number GI60709, was performed at:

Kauai Veterans Memorial Hospital
PO Box 337
Waimea, HI 96796

The system tested is identified as follows:

X-ray Control Model..... [redacted]

Serial Number.....[redacted]
Manufacture Date.....Unknown
X-ray Control Manufacturer.....[redacted]

During a telephone conversation on August 4, 1997, between you and Consumer Safety Officer Ronald C. Alexander, Los Angeles District X-ray Auditor, regarding serious noncompliances with the performance standards observed during the field test, you stated that you had corrected the noncompliances, as evidenced by your service record dated June 27, 1997. However, the field test, performed by the State of Hawaii under contract to FDA, determined that the system was defective in the following manner:

1. The x-ray production in the fluoroscopic mode was not controlled by a device that requires continuous pressure by the operator [21 CFR 1020.32(c)].

2. When the [redacted] recorder pack, installed into this fluorographic x-ray system is in default settings, the system emits electronic product radiation unnecessary to the accomplishment of its primary purpose. Criteria are provided in 21 CFR 1003.2(b) for considering this a defect related to electronic product radiation.

Manufacturers are required by 21 CFR 1020.30(g) to provide assemblers with instructions for assembly, installation, adjustment, and testing. The instructions must be adequate enough to assure compliance with the standards.

Manufacturers are required by 21 CFR 1020.30(h) to provide users with manuals and instruction sheets which include technical and safety information, including any radiological safety procedures and precautions which may be necessary because of unique features.

During the telephone notification from FDA on August 4, 1997, you stated that you were not involved in the [redacted] addition to the [redacted] x-ray control. The [redacted] accessory pack is manufactured by [redacted] On August 4, 1997, we received Report of Assembly (FDA-2579) number [redacted] dated March 14, 1997, which you faxed after that telephone notification regarding this serious noncompliance. We have reviewed your Report of Assembly and request that you provide clarification of your certification of assembly according to the instructions provided by the manufacturers.

Also, you stated on your Report of Assembly that this x-ray system was remanufactured by [redacted] You stated on your record of service number 03925 dated June 27, 1997, that manufacturer, [redacted] recommended the addition of equipment to prevent

the recurrence of unintended radiation emission by this system. You also stated that the manufacturer said that a voltage supply irregularity probably led to the occurrence of the problem, which you verified. Manufacturers are not held responsible under 21 CFR 1020.30(c) for a noncompliance of their products if the noncompliance is due solely to improper installation or assembly.

The system appears to have been manufactured after November 29, 1974, when certification became a requirement under 21 CFR subchapter J. Please verify the compliance status of the following when you correct the previously cited problems:

A. You certified, on March 14, 1997, that you adjusted and tested this system according to manufacturers instructions, on January 10, 1997, after its remanufacture by [redacted] Assemblers who install certified x-ray system components (manufactured after November 29, 1974), are required by 21 CFR 1020.30(d)(1) to file a Report of Assembly of a Diagnostic X-ray System (FDA-2579) within fifteen days following completion of the assembly. Your FDA-2579 submission failed to meet these criteria, in that it was submitted two months after installation.

B. You should include, in your response to this letter, the identification information required, and a copy of Report of Assembly number [redacted] correctly identifying the certification status of the system, in that no date of manufacture was present on the system [21 CFR 1010.3(a)(2)].

C. Our analysis of the field test data indicates that the system does not comply with the following item of the performance standard:

   i. The minimum field size was calculated to be greater than 84 square centimeters at a source-image receptor distance (SID,) with the longest dimension measured to be 17.2 centimeters. 21 CFR 1020.32(b)(2)(iv) requires that adjustment shall provide a field size containable within a 5 centimeter by 5 centimeter square at the maximum SID.

   ii. The x-ray field width exceeded the visible area of the image receptor by 3.8 percent of the source-image receptor distance (SID) at 100 centimeters for non-magnified image intensifier mode. 21 CFR 1020.32(b)(2) requires that the x-ray field may not exceed the visible area of the image receptor by more than 3 percent of the SID.

   iii. The sum of the excess length and width of the x-ray field greater than the visible area was measured to be 6.7 percent of the source-image receptor distance (SID) at

100 centimeters for non-magnified image intensifier mode. 21 CFR 1020.32(b)(2) requires that the x-ray field may not exceed the visible area of the image receptor by more than 4 percent of the SID.

In addition, we request that you, as the responsible assembler, immediately investigate the deviations from the performance standard in 21 CFR 1003 and 1004. Your action must provide for one of the following:

1. If the deviations and/or defects are due to improper assembly or installation, you must correct them at no charge to the user. You may either repair the system, replace the system, or refund the system's cost to the owner.

2. If you determine that the deviations and/or defects are caused by the factory-based manufacturer, you must notify the manufacturer and send documentation of such notification to this FDA office with appropriate evidence to support such a conclusion.

3. If you have evidence to establish that there is no failure to comply with the performance standard, that no defects exist, that the defects do not alter the safety of the product, or that the defects are directly attributable to user abuse or lack of maintenance, you may submit to this FDA office such evidence in accordance with 21 CFR 1003.30(a).

Please note that improper installation, including failure to follow installation instructions, which causes the system to be non-compliant with the Performance Standard, may cause the x-ray system to be adulterated. Under 501(c) of the Act, the system would not be of a quality represented by the labeling (including the certification statement).

Failure to promptly correct this violation can result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include seizure and/or injunction and/or the imposition of civil penalties as provided for in section 539 of the Act. Persons violating the Act are subject to civil penalties of up to $1,000 for each violation and up to a maximum of $300,000.

Within thirty working days of the receipt of this letter, you must notify this office in writing of the specific steps you have taken to correct the noted violations and preclude their recurrence. Your response should include the date corrective action was completed and copies of service records with other supporting documents showing the date(s) of service performed. If you do not respond within thirty working days, the FDA may consider you to be in violation of the Federal Food, Drug, and Cosmetic Act, sections 538(a)(2) and 538(a)(4) of Subchapter C - Electronic Product Radiation Control (formerly the Radiation

Control for Health and Safety Act of 1968), which may result in further enforcement action without notice. If corrective action cannot be completed within thirty working days, state the time within which it will be completed and explain the reasons for the delay.

Your response should be directed to:

John M. Doucette, Consumer Safety Officer
District X-ray Program Monitor
Food and Drug Administration
1431 Harbor Bay Parkway
Alameda, California 94502-7070

If you have any questions, please contact Mr. Doucette at (510) 337-6793.

Sincerely,

John M. Reves
Acting District Director
San Francisco District

cc: Kauai Veterans Memorial Hospital
P.O. Box 337
Waimea, HI 96796

[redacted]